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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,979	03/23/2005	Hisafumi Ikeda	4411/020	6393
170 7590 03/12/2008 RICHARD M. GOLDBERG 25 EAST SALEM STREET SUITE 419 HACKENSACK, NJ 07601				
EXAMINER				
PUTTLITZ, KARL J				
ART UNIT		PAPER NUMBER		
1621				
MAIL DATE		DELIVERY MODE		
03/12/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/528,979

**Applicant(s)**

IKEDA ET AL.

**Examiner**

KARL J. PUTTLITZ

**Art Unit**

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 2-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date various

## DETAILED ACTION

### *Specification*

The specification lacks a section regarding a brief description of the drawing.

### *Election/Restrictions*

Applicant's election without traverse of Group I, claim 1, in the reply filed on 2/1/2008 is acknowledged. Claims 2-12 are withdrawn from further consideration.

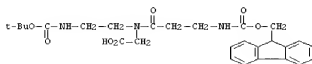
### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

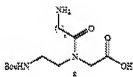
Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peptides 2000, Proceedings of the European Peptide Symposium, 26th, Montpellier, France, Sept. 10-15, 2000 (2001), Meeting Date 2000, pp. 403-404 (Peptides 2000), or WO 2002051797, as evidenced by U.S. Patent No. 7,282,575 to Ikeda (Ikeda I) in view of Peptide Synthesis in Ullmann's Encyclopedia of Industrial Chemistry (Ullmann's).

Peptides teaches the following compound:



See attached CAS online citation [retrieved 22 February 2008] from STN; Columbus, OH, USA.

Ikeda I teaches the following compound at column 7:



The difference between the compounds covered in the rejected claims and the compound disclosed by Peptides 2000 or Ikeda II is that the claimed compounds comprise different protecting groups, as opposed to the Fmoc groups in Peptides 2000 or the unprotected compound of Ikeda. However, protected amino groups are well within the technical grasp of those of ordinary skill, especially in the interest of peptide synthesis. It is for this proposition that the examiner joins Ullmann's, which discusses amino protecting groups, such as CBZ and Fmoc, see page 3.

In this regard, the claim would have been obvious because a person of ordinary skill has a good reason to pursue the known options of different protecting groups within his or her technical grasp. If this leads to the anticipated success, it is likely the product, not of innovation, but of ordinary skill and common sense.

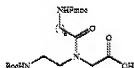
Specifically, the prior art contained a compound which differed from the claimed compound by the substitution of some protective groups with other protective groups; and the substituted protecting groups and their functions were known in the art; and one of ordinary skill in the art could have substituted one known protecting for another and the results of the substitution would have been predictable. Accordingly, the claim would have been obvious because the substitution of one known protecting group for another

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would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2003171396, published 6/20/2003, as evidenced by counterpart U.S. Patent No. 6,809,190 to Ikeda et al. (Ikeda II).

Ikeda II teaches the following compound at column 10:



The difference between the compounds covered in the rejected claims and the compound disclosed Ikeda II is that the claimed compounds comprise different protecting groups, as opposed to the Fmoc groups in Peptides 2000 or the unprotected compound of Ikeda. However, protected amino groups are well within the technical grasp of those of ordinary skill, especially in the interest of peptide synthesis. It is for this proposition that the examiner joins Ullmann's, which discusses amino protecting groups, such as CBZ and Fmoc, see page 3.

In this regard, the claim would have been obvious because a person of ordinary skill has a good reason to pursue the known options of different protecting groups within his or her technical grasp. If this leads to the anticipated success, it is likely the product, not of innovation, but of ordinary skill and common sense.

Specifically, the prior art contained a compound which differed from the claimed compound by the substitution of some protective groups with other protective groups; and the substituted protecting groups and their functions were known in the art; and one of ordinary skill in the art could have substituted one known protecting for another and the results of the substitution would have been predictable. Accordingly, the claim would have been obvious because the substitution of one known protecting group for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

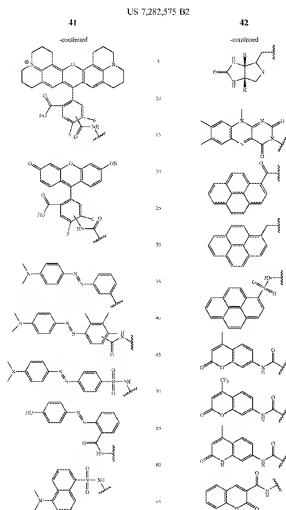
Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 12 are of copending Application No. 11/111022. Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims recite the same compounds differing only in the amine protecting groups, which are prima facie obvious, see 103 rejection, supra.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7282575. Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims recite the same compounds differing only in the amine protecting groups, which are prima facie obvious, see 103 rejection, supra. See

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especially, the following protecting groups at lines 35 and 50:





This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 11/915351. Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims recite compounds that particularly indicate those of claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-15 of copending Application No. 12/028622. Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims recite the same compounds differing only in the amine protecting groups, which are prima facie obvious, see 103 rejection, supra. claims recite compounds that particularly indicate those of claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl J. Puttlitz whose telephone number is (571) 272-0645. The examiner can normally be reached on Monday to Friday from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at telephone number (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Karl J. Puttlitz/

Primary Examiner, Art Unit 1621